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Prevalence of Structure Function Claims: 2006-2007 Food Label and Package Survey

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Abstract

The Food and Drug Administration (FDA) studies product labels from the United States (U.S.) food supply through the Food Label and Package Survey (FLAPS) to monitor industry responses to FDA regulations and policies on foods. The 2006-2007 FLAPS data were analyzed to obtain prevalence, food sources, and claim types of structure function (SF) claims. The SF claims describe the role of a nutrient or food component intended to maintain the normal structure or function of body (e.g., calcium builds strong bones). FDA selected regulated food products from the ACNielsen Strategic Planner sales database of the U.S. retail stores using a stratified, two-stage design with selection probabilities proportional to nationally estimated sales dollars. Products were purchased from retail stores across the U.S. and the detailed product label information was recorded. FDA calculated product sampling weights based on sales data so that the FLAPS estimate will be generalizable to the foods sold in all U.S. retail stores The FLAPS database contains label information for 1,227 foods in 57 product groups. The weighted prevalence of the FLAPS foods with at least one SF claim was 5.5%, of which approximately 1/3 had two or more SF claims. There were about 30 different types of SF claims and commonly found SF claims include claims about healthy bones and teeth, baby's brain and eye development, healthy weight, immune system, and healthy cholesterol level. The SF claims were found commonly in the following product groups: infant formulas, cheeses, yogurts, cold cereals, refrigerated and shelf-stable juices and drinks. These results demonstrate the usefulness of the FLAPS data as an FDA's monitoring tool to assess compliance with food label-related laws and regulations and to plan for future policy making.

Peer-review under responsibility of the National Nutrient Databank Steering Committee

Keywords: Food Label, FLAPS, Structure Function Claims

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1. Introduction

Since 1976, the Food and Drug Administration (FDA) has been conducting Food Label and Package Survey (FLAPS) periodically to obtain food label characteristics of FDA-regulated packaged foods.[1-4] FDA uses the FLAPS data for various regulatory activities on foods including initiating new regulations, modifying the existing regulations, and identifying foods for food safety and other concerns. The 2006-2007 FLAPS captures almost all food label characteristics of packaged foods, including net weight, ingredients, nutrition information, claims, and other consumer statements.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or FDA regulations, three categories of claims can be used on food and dietary supplement labels: nutrient content claims; health claims; and structure and function (SF) claims. Nutrient content claims either directly or by implication characterize the level of a nutrient in the food (e.g., "low fat," "high in vitamin C," or "contains 100 calories"). Health claims describe a relationship between a food substance and reduced risk of a disease or health-related condition (e.g., "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease"). The SF claims describe the role of a nutrient or food component intended to maintain the normal structure or function of body (e.g., calcium builds strong bones). The claim language used in the SF claims is different from that of health claims or claims for drugs which are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (FD&C Act, Section 201(g)). The Dietary Supplement Health and Education Act of 1994 established specific regulatory requirements and procedures for SF claims on dietary supplement products (FD&C Act, Section 403(r)(6)), whereas, for SF claims on conventional foods such as packaged food products, the general provision on misbranding and false and misleading labeling applies (FD&C Act, Section 403(a)).

The claim prevalence was reported previously for the 1997 FLAPS (nutrient content claims and health claims),[1] the 2000-2001 FLAPS (nutrient content claims, SF claims, and health claims)[2] and the 2006-2007 FLAPS (nutrient content claims and health claims).[4] The current study fills the gap in the understanding of claims from the 2006-2007 FLAPS by providing the information on SF claims.

2. Methods

The sampling frame for the 2006-2007 FLAPS consisted of consecutive 44 weeks of scanner sales from food stores with annual sales of over $2 million, ending in November 2005, from the ACNielsen Strategic Planner (CAN) sales database (ACN).[5] Nielsen company collects food scanner sales data from more than 3,000 food stores with over $2 million in all commodity volume, across all geographical locations. At the first stage of the FLAPS sampling, brands were selected without replacement within 57 product groups (e.g., baby foods, beverages, dairy products) by probability proportional to dollar sales (PPS). Sample sizes for each product group were determined using allocation proportional to dollar sales of the group. For each brand selected in the first stage, one product was selected within brand by PPS. Products that were in Nielsen's dietary supplement group or packaged meat group were not included in the sampling. The selected products from the sales data were purchased at retail stores and the detailed food label information was obtained by reviewing the product packages. Substitutes were chosen as much as possible for products that could not be located and products that were found to be regulated by the United States Department of Agriculture. The non-response rate (i.e., the percentage of sampled products that were not included in the final FLAPS database) was 5.5% (72 products).[3] The total number of products that were included in the final FLAPS database was 1,227. Sampling weights were calculated for each product in the final database and represent the sales dollars that the product represents in the target population. The weights incorporate the probabilities of selection from the two stages of sampling and an adjustment to compensate for non-response. The prevalence estimates are weighted estimates.

3. Results

Among 1,227 products in the FLAPS database, 5.5% had at least one structure function claim (of which, 70.2% had one claim, 24.1% had two claims, 3.6% had three claims, and 2.1% had four or more claims). Baby foods,

cheeses, cold cereals, refrigerated and shelf-stable juices, and dairy miscellaneous products (yogurts and a powdered milk additive) accounted for 77.4% of all products with SF claims (Figure 1).

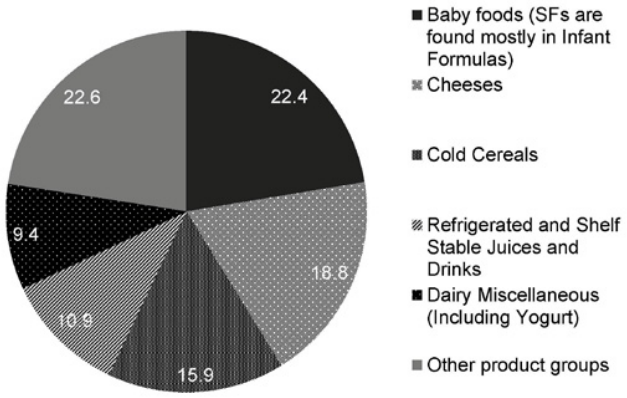

Fig. 1. Percentage of SF Claims across Product Groups. The SF claims describe the role of a nutrient or food component intended to maintaithe normal structure or function of body.

Within product group analysis, baby foods showed the highest percentage of SF claims (68.0%) followed by cold cereals (24.8%) and cheeses (18.8%) (Figure 2). The most commonly found claims were: baby's brain and eye development which was found in 65.3% of baby foods, healthy weight which was found in 11.7% of cold cereals, and strong bones and teeth which was found in 18.8% of cheeses.

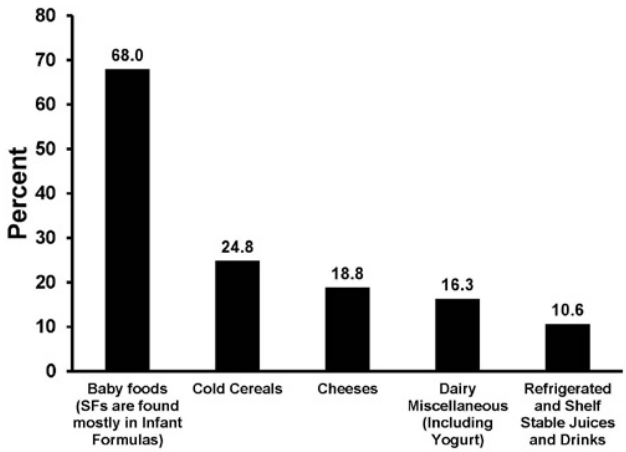

Fig. 2. Percentage of SF Claims within Each Product Group (The product groups that had less than 20 foods were excluded from this presentation. The SF claims describe the role of a nutrient or food component intended to maintain the normal structure or function of body.

Among all products, there were about 30 different types of SF claims. The five most commonly found SF claims were claims about strong bones and teeth, baby's brain and eye development, healthy weight, immune system, and healthy cholesterol level (Figure 3). The most commonly mentioned nutrient/food in these claims was calcium (for strong bones), docosahexaenoic acid (DHA) and arachidonic acid (ARA) (for baby's brain and eye development), whole grain foods (for healthy weight), vitamin C (for immune system), and soluble fiber (for healthy cholesterol level).

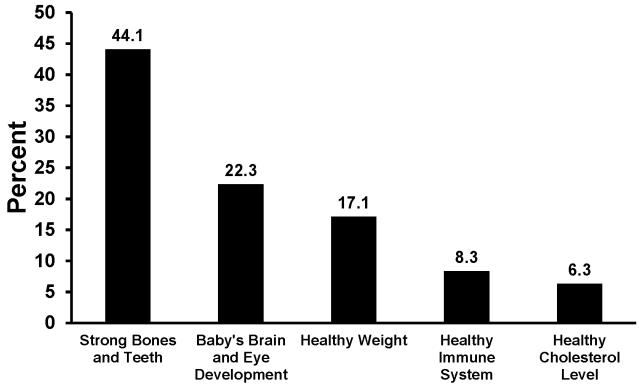

Fig. 3. Percentage of Top Five SF Claims among Products with SF Claims.

4. Conclusions

With the addition of SF claim prevalence that the current study provided, the prevalence estimates for three claims (i.e., health claims, SF claims, and nutrient content claims) are complete for the 2006-2007 FLAPS. There appear to be consistent findings in the claim pattern among the three past FLAPS (1997 FLAPS, 2000 FLAPS, and 2006-2007 FLAPS). The results from the 1997 FLAPS were health claims (4.2%) and nutrient content claims (38.7%).[1] The results from the 2000-2001 FLAPS were health claims (4.4%), SF claims (6.2%), and nutrient content claims (49.7%).[2] The results from the 2006-2007 FLAPS were health claims (4.8%),[4] SF claims 5.5% (current study), nutrient content claims (53.2%).[4] These survey results showed that nutrient content claims were the predominant type of claims among the three claims and SF claims were used slightly more than health claims but

both of these claims were much less frequently used than nutrient content claims. Another consistent finding among these surveys is the food sources of SF claims. In both the 2000-2001 FLAPS[2] and the 2006-2007 FLAPS (current study), SF claims were commonly found in baby foods, shelf-stable juices and drinks, cold cereals, and refrigerated juices and drinks.

The analysis that was performed in the current study but not in the previous surveys is the prevalence estimate of SF claim types within product groups. Certain types of SF claims were commonly, sometimes exclusively, found in some product groups (e.g., calcium for strong bones and teeth among cheese products, DHA and ARA for baby's brain and eye development). Comparing prevalence estimates across FLAP survey cycles using hypothesis testing is difficult because the surveys are not consistent in their sampling methodologies. FDA is working on streamlining the sampling process from cycle to cycle to make such comparisons possible in the future. The use of the same sampling method, the same source of sales data, and a larger sample size will make the future FLAPS data more useful for FDA for application in regulatory work on foods.

The food label characteristics that FDA obtains from the FLAPS data provide valuable resources by which FDA assesses compliance with applicable laws and regulations and plans for future regulatory strategies that promote public health through food label.

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